



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,371	10/05/2004	Hans-Ulrich Petereit	257546US0X PCT	8786

22850 7590 03/19/2008
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

BERNSHTEYN, MICHAEL

ART UNIT	PAPER NUMBER
----------	--------------

1796

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

03/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No. 10/510,371	Applicant(s) PETEREIT ET AL.	
	Examiner MICHAEL M. BERNSHTEYN	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/09/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action follows a response filed on January 9, 2008. Claims 1, 3 and 11 have been amended; no claims have been cancelled or added.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2008 has been entered.
3. In view of the amendment(s) and remarks the rejection of claim 1 under 35 U.S.C. § 112, 1st paragraph and the rejection of claims 11 and 19 under 35 U.S.C. § 112, 2nd paragraph have been withdrawn.
4. Claims 1-12, 19 and 20 are active.

Claim Rejections - 35 USC § 103

5. The text of this section of Title 35 U.S.C. not included in this action can be found in a prior Office Action.
6. Claims 1-12, 19 and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable as obvious over Haddleton et al. (U.S. Patent 5,804,632) in view of Rehmer et al. (U.S. Patent 6,225,401), for the rationale recited in paragraph 8 of Office Action dated September 26, 2006, and comments below.

Response to Arguments

7. Applicants traverse the rejection under 35 U.S.C. §103(a) of claims 1-12, 19 and 20 as being unpatentable as obvious over Haddleton et al. (U.S. Patent 5,804,632) in view of Rehmer et al. (U.S. Patent 6,225,401). Applicant's arguments filed on January 9, 2008 have been fully considered but they are not persuasive.

8. Regarding the Applicants arguments that if methacrylic acid is an acid comonomer, and if alkyl esters of (meth) acrylic acid are non acid functional comonomers, these ranges would appear to overlap the monomer content ranges of Claim 1 (page 8, 2nd paragraph), it is noted that the rejection was made not under 35 U.S.C. § 102 but not under 35 U.S.C. § 103(a) because “[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Therefore it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per ***In re Boesch and Slaney*** 205 USPQ 215 (CCPA 1980).

Furthermore, it is worth to mention that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” ***In re Aller***, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie*

Art Unit: 1796

obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%).).

9. In response to the Applicants arguments that Rehmer discloses a process for producing copolymers of acrylic and/or (meth)acrylic acid by emulsion polymerization instead of by CCT process used by Haddleton, and the obviousness rejection is based on substituting the emulsion polymerization method of Rehmer for the CCT process of Haddleton for the purpose of obtaining the polymers of the invention which do not contain transition metal complexes (page 9, the last paragraph), it is noted that instant claim 1 is a product claim and it recites a pH-sensitive polymer, but not a process for preparing a pH-sensitive polymer. Therefore, it is the examiner position to believe that the instantly claimed product , i.e. pH-sensitive polymer of Haddleton and Rehmer is substantially the same as pH-sensitive polymer recited in claim 1, even though obtained by a different process, consult *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

10. It appears that the focal argument resides in the contention that there is no motivation for selecting polymers which brings about at least 60% haemolysis at pH 5,5 and less than 5% haemolysis of human red blood cells at pH 7.4 (page 10, 2nd paragraph), the rejection was made in the sense of *In re Spada*, 911 F 2d 705, 709 15 USPQ 1655, 1658 (Fed. Cir. 1990), which settles that when the claimed compositions are not novel, they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in prior art.

Therefore, the properties governing the claimed composition comprising brings about at least 60% haemolysis at pH 5,5 and less than 5% haemolysis of human red blood cells at pH 7.4, at a concentration of 150 µg/ml in a cytotoxicity test with human red blood cells, are inherently the same as or rendered obvious over Haddleton and Rehmer, since Haddleton and Rehmer's polymer contains essentially the same methacrylic acid units and esters of methacrylic acid, as instantly claimed and their weight ratio, initiators, emulsifier, process of aqueous emulsion polymerization producing such polymers and the same range of molecular weight, etc.

Since the USPTO does not have proper equipment to do the analytical test the burden is now shifted to the applicant to prove otherwise. ***In re Best***, 195 USPQ 430, (CCPA 1977).

Even assuming that the claims are not anticipated by the references, it would have been obvious to one of ordinary skill in the art to make the polymer having the claimed properties because it appears that the reference generically embrace the claimed subject matter and the person of ordinary skill in the art would have expected all embodiments of the reference to work. Applicants have not demonstrated that the differences, if any, between the claimed subject matter and the subject matter of the prior art examples give rise to unexpected products.

11. In response to Applicants arguments that “while page 7, line 4 of the final Official Action mentions the term “result effective variable” it does not indicate that the pH-sensitive properties required by the polymers of the invention are results-effective variables. It cannot, since pharmacological use of the Haddleton and Rehmer polymers

Art Unit: 1796

is not contemplated. Thus, the argument with regard to optimizing a results effective is immaterial to the pH-sensitivity limitations in Claim 1" (page 11, 2nd paragraph), it is noted the following.

The Examiner used the term "result effective variables" in final rejection only regarding the amount of methacrylic acid, methacrylates and acrylates in the copolymer, not to the pH-sensitive polymer's properties such as at least 60% haemolysis at pH 5,5 and less than 5% haemolysis of human red blood cells at pH 7.4, as incorrectly was mentioned by the Applicants. It was clearly noted that **the amount of methacrylic acid, methacrylates and acrylates** in the copolymer **is a result effective variable**, and therefore, it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per *In re Boesch and Slaney* 205 USPQ 215 (CCPA 1980). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

For the above reasons, it is believed that the rejections should be sustained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL M. BERNSHTEYN whose telephone number is (571)272-2411. The examiner can normally be reached on M-Th 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796

/Michael M. Bernshteyn/
Examiner, Art Unit 1796

/M. M. B./
Examiner, Art Unit 1796

Application/Control Number: 10/510,371
Art Unit: 1796

Page 8